

**PATENTS**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appl. No.: : 10/646,970  
Applicant : Carol J. Phelps  
Conf. No.: : 3048  
Filed : August 21, 2003  
TC/A.U. : 1600/1632  
Examiner : Joseph T. Woitach  
Title : Porcine Animals Lacking Any Expression Of Functional Alph 1,3  
Galactosyltransferase  
  
Docket No.: : 10758.105009 REV1004  
Customer No. : 20786

Mail Stop AMENDMENT  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

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Sir:

Applicant cites the information on the attached Form PTO/SB/08A, "Information Disclosure Statement by Applicant," pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98. Applicant has enclosed a copy of each cited foreign patent document and non-patent literature.

The citation of this information does not constitute an admission of priority or that any cited item is available as a reference, or a waiver of any right the applicants may have under applicable statutes, Rules of Practice in patent cases, or otherwise.

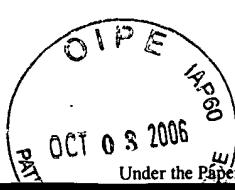
Respectfully submitted,



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Rebecca J. Kaufman  
Reg. No. 44,819

Date: September 25, 2006

KING & SPALDING LLP  
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Intellectual Property Dept. - Patents, 34<sup>th</sup> Floor  
Atlanta, Georgia 30309-3521



Substitute for Form 1449A PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 10 Attorney Docket Number 10758.105009 REV 1004

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### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code (if known)			
	AA	4,797,368	A	Carter <i>et al.</i>	01-10-1989	
	AB	4,863,852	A	Wilkins <i>et al.</i>	09-05-1989	
	AC	5,175,383	A	Leder <i>et al.</i>	12-29-1992	
	AD	5,354,768	A	Terada <i>et al.</i>	10-11-1994	
	AE	5,474,935	A	Chatterjee <i>et al.</i>	12-12-1995	
	AF	5,523,226	A	Wheeler	06-04-1996	
	AG	5,681,731	A	Lebkowski <i>et al.</i>	10-28-1997	
	AH	5,714,353	A	Pathak <i>et al.</i>	02-03-1998	
	AI	5,821,117	A	Sandrin <i>et al.</i>	10-13-1998	
	AJ	5,849,991	A	d'Apice <i>et al.</i>	12-15-1998	Sequence 8
	AK	5,850,004	A	MacMicking <i>et al.</i>	12-15-1998	
	AL	5,922,601	A	Baetscher <i>et al.</i>	07-13-1999	
	AM	5,942,435	A	Wheeler	06-06-1995	
	AN	6,153,428	A	Gustafsson <i>et al.</i>	11-28-2000	
	AO	6,235,969	B1	Stice <i>et al.</i>	05-22-2001	
	AP	6,258,998	B1	Damiani <i>et al.</i>	07-10-2001	
	AQ	6,331,658	B1	Cooper <i>et al.</i>	12-18-2001	
	AR	2001/0055584	A1	McKenzie <i>et al.</i>	12-27-2001	
	AS	6,413,769	B1	Gustafsson <i>et al.</i>	07-02-2002	
	AT	6,455,037	B1	Ioannou <i>et al.</i>	09-24-2002	
	AU	2002/0031494	A1	Sandrin <i>et al.</i>	03-14-2002	
	AV	2002/0152488	A1	Cooper <i>et al.</i>	10-17-2002	
	AW	2003/0014770	B1	Gustafsson <i>et al.</i>	01-16-2003	
	AX	2003/0203427	A1	Koike	10-30-2003	
	AY	6,849,448	B1	D'Apice <i>et al.</i>	02-01-2005	
	AZ	2005/0120400	A1	Day <i>et al.</i>	06-02-2005	

### FOREIGN PATENT DOCUMENTS

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		Office <sup>3</sup>	Number	Kind Code <sup>2</sup> (if known)				
	AAA	EP	0669829	B1	Biotransplant, Inc.	08-08-2001		
	AAB	JP	1994-253856	A1	MASAYA <i>et al.</i> ,	09-13-1994	Seq ID No.1 Alignment	
	AAC	WO	94/02616	A1	Regents of Univ. of Michigan	02-03-1994		

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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*Complete if Known*

Sheet <b>2</b> of <b>10</b>				Application Number <b>10/646,970</b>
				Filing Date <b>August 21, 2003</b>
				First Named Inventor <b>Carol J. Phelps</b>
				Group Art Unit <b>1632</b>
				Examiner Name <b>Joseph T. Woitach</b>
				Attorney Docket Number <b>10758.105009 REV 1004</b>

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		Office <sup>2</sup>	Number	Kind Code <sup>3</sup> (if known)				
	BA	WO	94/09803	A1	Biotransplant Inc.	05-11-1994		
	BB	WO	94/21799	A1	Austin Research Inst.	09-29-1994		
	BC	WO	94/24870	A1	Biotransplant, Inc.	11-10-1994		
	BD	WO	95/20661	A1	Bresatec <i>et al.</i>	08-03-1995		
	BE	WO	95/28412	A1	Biotransplant Inc. <i>et al.</i>	10-26-1995		
	BF	WO	95/34202	A1	Alexion Pharmaceuticals Inc.; Austin Research Institute	12-21-1995		
	BG	WO	96/06165	A1	The General Hosp. Corp.; Biotransplant, Inc.	02-29-1996		
	BH	WO	96/28967	A1	Chihiro Koike	09-26-1996		
	BI	WO	96/37602	A1	Diacrin, Inc.	11-28-1996		
	BJ	WO	96/40244	A1	Biotransplant, Inc.	12-19-1996		
	BK	WO	97/16064	A1	Austin Research Institute	05-09-1997		
	BL	WO	97/16727	A1	Biotransplant Inc.	05-09-1997		
	BM	WO	98/05768	A1	Austin Research Institute	02-12-1998		
	BN	WO	98/07444	A1	Biotransplant, Inc.	02-26-1998		
	BO	WO	98/07837	A1	Austin Research Institute	02-26-1998		
	BP	WO	98/33528	A2	Biotransplant Inc.	08-06-1998		
	BQ	WO	99/09141	A1	Biotransplant, Inc.	02-25-1999		
	BR	WO	99/09163	A1	Biotransplant, Inc.	02-25-1999		
	BS	WO	99/19469	A1	Biotransplant, Inc.	04-22-1999		
	BT	WO	99/21415	A1	Biotransplant Inc.	05-06-1999		
	BU	WO	99/49029	A1	AG-Gene Australia Ltd.	09-30-1999		
	BV	WO	00/06194	A2	Biotransplant, Inc.	02-10-2000		
	BW	WO	00/11147	A1	Biotransplant Inc.	03-02-2000		
	BX	WO	00/51424	A2,3	PPL Therapeutics	09-08-2000		
	BY	WO	01/23541	A2	Alexion Pharmaceuticals, Inc.	04-05-2001		
	BZ	WO	01/30992	A2	University of Pittsburgh	05-03-2001		
	BAA	WO	02/10337	A2	Ifigen, Inc.	02-07-2002		
	BAB	WO	03/055302	A1	University of Missouri	07-10-2003		
	BAC	WO	04/016742	A2	Immerge Biotherapeutics Inc.	02-26-2004		

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/646,970
(use as many sheets as necessary)				Filing Date	August 21, 2003
Sheet	3	of	10	First Named Inventor	Carol J. Phelps
				Group Art Unit	1632
				Examiner Name	Joseph T. Woitach
				Attorney Docket Number	10758.105009 REV 1004

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**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	CA	AYARES, D., <i>et al.</i> , (PPL Therapeutics, Inc.), "Gene targeting in livestock," Transgenic Animal Research Conference (hosted by Univ. of Calif. at Davis biotechnology program, at the Granlibakken Conf. Ctr. in Tahoe City, CA, July 1999 [ <a href="http://www.biotech.ucdavis.edu">http://www.biotech.ucdavis.edu</a> ]), abstract at p. 20.	
	CB	AYARES, D., <i>et al.</i> , (PPL Therapeutics, Inc.), "Gene targeting in livestock for production of novel biopharmaceuticals," <i>ISB News Report</i> (published by Information Systems for Biotechnology), Nov. 1999:5-6, at <a href="http://www.isb.vt.edu/news/1999/Nov44.pdf">http://www.isb.vt.edu/news/1999/Nov44.pdf</a>	
	CC	AYARES, D., <i>et al.</i> , "Cloning pigs deficient in $\alpha$ 1,3 galactosyltransferase," <i>Graft</i> , 4(1):80-83 (2001).	
	CD	BACH, F.H., <i>et al.</i> , "Delayed xenograft rejection," <i>Immunol. Today</i> , 17(8):379-384 (August 1996).	
	CE	BETTHAUSER, J., <i>et al.</i> , "Production of cloned pigs from in vitro systems," <i>Nature Biotechnology</i> , 18(10):1055-1059 (October 2000).	
	CF	BONDIOLI, K., <i>et al.</i> , "Cloned pigs generated from cultured skin fibroblasts derived from a H-transferase transgenic boar, <i>Molecular Reproduction and Development</i> , 60(2):189-195 (October 2001).	
	CG	BRANDON, E.P., <i>et al.</i> , "targeting the mouse genome: A compendium of knockouts (part I)," <i>Current Biology</i> , 5[6]:625-634 (1995).	
	CH	BRANDON, E.P., <i>et al.</i> , "targeting the mouse genome: A compendium of knockouts (part II)," <i>Current Biology</i> , 5[7]:758-765 (1995).	
	CI	BRANDON, E.P., <i>et al.</i> , "targeting the mouse genome: A compendium of knockouts (part III)," <i>Current Biology</i> , 5[8]:873-881 (1995).	
	CJ	BUTLER, D., "Xenotransplant experts express caution over knockout piglets," <i>Nature</i> , 415(6868):103-104 (January 10, 2002).	
	CK	CAPECCHI, M.R., <i>et al.</i> , "Altering the genome by homologous recombination," <i>Science</i> , 244(4910):1288-1292 (June 16, 1989).	
	CL	CLARK, A.J., <i>et al.</i> , "Gene targeting in livestock: a preview," <i>Transgenic Res.</i> , 9(4-5):263-275 (2000).	
	CM	CLARK, G.F., <i>et al.</i> , "Toxin A from Clostridium difficile binds to rabbit erythrocyte glycolipids with terminal Gal alpha 1-3Gal beta 1-4GlcNAc sequences," <i>Arch.Biochem.Biophys.</i> , 257(1):217-229, (Aug. 15, 1987).	
	CN	COOPER, D.K., <i>et al.</i> , "Oligosaccharides and discordant xenotransplantation," <i>Immunol. Rev.</i> , 141:31-58 (October 1994).	
	CO	COOPER, D.K.C., <i>et al.</i> , "Genetically engineered pigs," <i>Lancet</i> , 342:682-683 (Sept. 11, 1993).	
	CP	COSTA, C., <i>et al.</i> , "Expression of the human $\alpha$ 1,2-fucosyltransferase in transgenic pigs modifies the cell surface carbohydrate phenotype and confers resistance to human serum-mediated cytolysis," <i>FASEB J.</i> , 13:1762-1773 (Oct. 1999).	

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### OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	DA	DABKOWSKI, P.L., <i>et al.</i> , "Characterisation of a cDNA clone encoding the pig alpha 1,3 galactosyltransferase: implications for xenotransplantation," <i>Transplant Proc.</i> , 25(5):2921 (October 1993).	
	DB	DABKOWSKI, P.L., <i>et al.</i> , "Isolation of a cDNA clone encoding the pig alpha 1,3 galactosyltransferase," <i>Transplant Proc.</i> , 26(3):1335 (June 1994).	
	DC	DAI, Y., <i>et al.</i> , "Targeted disruption of the $\alpha$ 1,3-galactosyltransferase gene in cloned pigs," <i>Nature Biotechnology</i> , 20:251-255 (March 2002).	
	DD	DALMASSO, A.P., <i>et al.</i> , "Inhibition of complement-mediated endothelial cell cytotoxicity by decay-accelerating factor: Potential for prevention of xenograft hyperacute rejection," <i>Transplantation</i> , 52(3):530-533 (Sept. 1991).	
	DE	DALMASSO, A.P., <i>et al.</i> , "Reaction of complement with endothelial cells in a model of xenotransplantation," <i>Clin. Exp. Immunol.</i> , 86:31-35 (1991).	
	DF	D'APICE, A.J., <i>et al.</i> , "Two genetic approaches to the galactose alpha 1,3 galactose xenoantigen," <i>Transplant Proc.</i> , 28(2):540 (April 1996).	
	DG	DENNING, C., <i>et al.</i> , "Gene targeting in primary fetal fibroblasts from sheep and pig," <i>Cloning Stem Cells</i> , 3(4):221-231 (2001).	
	DH	DENNING, C., <i>et al.</i> , "Deletion of the $\alpha$ (1,3)galactosyl transferase (GGTA1) gene and the prion protein ( <i>PrP</i> ) gene in sheep," <i>Nature Biotechnology</i> , 19:559-562 (June 2001).	
	DI	FABRE, J.W., "Nudging xenotransplantation towards humans," <i>Nature Med.</i> , 1(5):403-404 (May 1995).	
	DJ	GALILI, U., "The $\alpha$ -gal epitope (Gal $\alpha$ -3Gal $\beta$ -4GlcNAc-R) in xenotransplantation," <i>Biochimie</i> , 83:557-563 (2001).	
	DK	GALILI, U., <i>et al.</i> , "Evolution and pathophysiology of the human natural anti-alpha-galactosyl IgG (anti-Gal) antibody," <i>Springer Semin. Immunopathol.</i> , 15(2-3):155-171 (1993).	
	DL	GALILI, U., <i>et al.</i> , "Evolutionary relationship between the natural anti-Gal antibody and the Gal alpha 1----3Gal epitope in primates," <i>Proc. Natl. Acad. Sci. USA</i> , 84(5):1369-1373 (March 1987).	
	DM	GALILI, U., <i>et al.</i> , "Human natural anti-alpha-galactosyl IgG. II. The specific recognition of alpha (1----3)-linked galactose residues," <i>J. Exp. Med.</i> , 162(2):573-582 (August 1, 1985).	
	DN	GALILI, U., <i>et al.</i> , "Man, apes, and old world monkeys differ from other mammals in the expression of $\alpha$ -galactosyl epitopes on nucleated cells," <i>J. Biol. Chem.</i> , 263(33):17755-17762 (Nov. 25, 1988).	
	DO	GASSMANN, M., <i>et al.</i> , "Maintenance of an extrachromosomal plasmid vector in mouse embryonic stem cells," <i>Proc. Natl. Acad. Sci. USA</i> , 92(5):1292-1296 (February 28 1995).	
	DP	GASTINEL, L.N., <i>et al.</i> , "Bovine $\alpha$ 1,3-galactosyltransferase catalytic domain structure and its relationship with ABO histo-blood group and glycosphingolipid glycosyltransferases," <i>EMBO Journal</i> , 20(4):638-649 (2001).	

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	EA	HAMMER, R.E., <i>et al.</i> , "Production of transgenic rabbits, sheep and pigs by microinjection," <i>Nature</i> , 315(6021):680-683 (June 20-26, 1985).	
	EB	HANCOCK, W., "Hyde Park Speakers Corner: Xeno-stagnation," <i>AST Newsletter</i> , 6(3):31-33 (Summer 1999) (American Society of Transplantation, Moorestown, NJ) (also published at <a href="http://www.a-s-t.org/library/newsArchive/vol6-3/hydepark.htm">http://www.a-s-t.org/library/newsArchive/vol6-3/hydepark.htm</a> ).	
	EC	HARDUIN-LEPERS, A., <i>et al.</i> , "Characterization of two cis-regulatory regions in the murine beta 1,4-galactosyltransferase gene. Evidence for a negative regulatory element that controls initiation at the proximal site," <i>J. Biol. Chem.</i> , 268(19):14348-14359 (July 5, 1993).	
	ED	HARRISON, S.J., <i>et al.</i> , "Efficient generation of $\alpha$ (1,3) galactosyltransferase knockout porcine fetal fibroblasts for nuclear transfer," <i>Transgenics Research</i> , 11:143-150 (2002).	
	EE	HASTY, P., <i>et al.</i> , "The length of homology required for gene targeting in embryonic stem cells," <i>Mol. Cell Biol.</i> , 11(11):5586-5591 (November 1991).	
	EF	HAYASHI, S., <i>et al.</i> , "Adenovirus-mediated gene transfer of antisense ribozyme for alpha (1,3)galactosyltransferase gene and alpha (1,2)fucosyltransferase gene in xenotransplantation," <i>Transplant Proc.</i> , 29(4):2213 (June 1997).	
	EG	HENNET, T., "The galactosyltransferase family," <i>Cell. Mol. Life Sci.</i> , 59:1081-1095 (2002).	
	EH	JOYNER, A.L., "Production of a mutation in mouse En-2 gene by homologous recombination in embryonic stem cells," <i>Nature</i> , 338(6211):153-156 (March 9, 1989).	
	EI	JOZIASSE, D.H., <i>et al.</i> , "Bovine $\alpha$ 1 $\rightarrow$ 3-galactosyltransferase: Isolation and characterization of a cDNA clone: Identification of homologous sequences in human genomic DNA," <i>J. Biol. Chem.</i> , 264(24):14290-14297 (Aug. 25, 1989).	
	EJ	JOZIASSE, D.H., <i>et al.</i> , "Characterization of an $\alpha$ 1 $\rightarrow$ 3-galactosyltransferase homologue on human chromosome 12 that is organized as a processed pseudogene," <i>The Journal of Biological Chemistry</i> , 266(11):6991-6998 (April 15, 1991).	
	EK	JOZIASSE, D.H., <i>et al.</i> , "Murine $\alpha$ 1 $\rightarrow$ 3-galactosyltransferase: A single gene locus specifies four isoforms of the enzyme by alternative splicing," <i>J. Biol. Chem.</i> , 267(8):5534-5541 (March 15, 1992).	
	EL	JOZIASSE, D.H., <i>et al.</i> , "Xenotransplantation: the importance of the Galalpha1,3Gal epitope in hyperacute vascular rejection," <i>Biochim. Biophys. Acta</i> , 1455(2-3):403-418 (October 8, 1999).	
	EM	JUST, I., <i>et al.</i> , "The low molecular mass GTP-binding protein rho is affected by toxin A from <i>Clostridium difficile</i> ," <i>J. Clin. Invest.</i> , 95:1026-1031 (1995).	
	EN	KATAYAMA, A., <i>et al.</i> , "Porcine $\alpha$ -1,3-galactosyltransferase: full length cDNA cloning, genomic organization, and analysis of splicing variants," <i>Glyconjugate Journal</i> , 15:583-589 (1998).	

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Substitute for form 1449A/PTO				<i>Complete if Known</i>	
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				Filing Date	August 21, 2003
				First Named Inventor	Carol J. Phelps
				Group Art Unit	1632
				Examiner Name	Joseph T. Woitach
Sheet	6	of	10	Attorney Docket Number	10758.105009 REV 1004

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**OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS**

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	FA	KELLY, R.J., <i>et al.</i> , "Sequence and expression of a candidate for the human Secretor blood group alpha (1,2)fucosyltransferase gene (FUT2). Homozygosity for an enzyme-inactivating nonsense mutation commonly correlates with the non-secretor phenotype," <i>J. Biol. Chem.</i> , 270(9):4640-4649 (Mar. 3, 1995).	
	FB	KILBY, N.J., <i>et al.</i> , "Site-specific recombinases: tools for genome engineering," <i>Trends in Genetics</i> , 9(12):413-421 (December 1993)..	
	FC	KOIKE, C., <i>et al.</i> , "Comparison of the regulatory regions of the of $\alpha$ 1,3galactosyltransferase gene between murine and porcine species," <i>Transplantation Proceedings</i> , 33:710-711 (2001).	
	FD	KOIKE, C., <i>et al.</i> , "Direct gene replacement of the mouse $\alpha$ (1,3)-galactosyltransferase gene with human $\alpha$ (1,2)-fucosyltransferase gene: Converting $\alpha$ -galactosyl epitopes into H antigens," <i>Xenotransplantation</i> , 4:147-153 (1997).	
	FE	KOIKE, C., <i>et al.</i> , "Introduction of $\alpha$ (1,2)-fucosyltransferase and its effect on $\alpha$ -Gal epitopes in transgenic pig," <i>Xenotransplantation</i> , 3:81-86 (1996).	
	FF	KOIKE, C., <i>et al.</i> , "Isolation of the regulatory regions and genomic organization of the porcine $\alpha$ 1,3-galactosyltransferase gene," <i>Transplantation</i> , 70(9):1275-1283 (Nov. 15, 2000).	
	FG	KOIKE, C., <i>et al.</i> , "Molecular basis of evolutionary loss of the $\alpha$ 1,3-galactosyltransferase gene in higher primates," <i>J. Biol. Chem.</i> , 277(12):10114-101120 (March 22, 2002).	
	FH	LAI, L., <i>et al.</i> , "Production of $\alpha$ -1,3-galactosyltransferase knockout pigs by nuclear transfer cloning," <i>Science</i> 295:1089-1092 (February 8, 2002) and supplementary data, <i>Science Express</i> , January 3, 2002.	
	FI	LARSEN, R.D., <i>et al.</i> , "Frameshift and nonsense mutations in a human genomic sequence homologous to a murine UDP-Gal:beta-D-Gal(1,4)-D-GlcNAc alpha(1,3)-galactosyltransferase cDNA," <i>J. Biol. Chem.</i> , 265(12):7055-7061 (April 25, 1990).	
	FJ	LARSEN, R.D., <i>et al.</i> , "Isolation of a cDNA encoding a murine UDPgalactose:beta-D-galactosyl- 1,4-N-acetyl-D-glucosaminide alpha-1,3-galactosyltransferase: expression cloning by gene transfer," <i>Proc. Natl. Acad. Sci., U.S.A.</i> , 86(21):8227-8231 (November 1989).	
	FK	LARSEN, R.D., <i>et al.</i> , "Molecular cloning, sequence, and expression of a human GDP-L-fucose:beta-D-galactoside 2-alpha-L-fucosyltransferase cDNA that can form the H blood group antigen," <i>Proc. Natl. Acad. Sci., U.S.A.</i> , 87(17):6674-6678 (September 1990).	
	FL	LO, N.W., <i>et al.</i> , "Transcription of the beta-galactoside alpha 2,6-sialyltransferase gene in B lymphocytes is directed by a separate and distinct promoter," <i>Glycobiology</i> , 6(3):271-279 (April 1996).	
	FM	LUCKOW, V.A., <i>et al.</i> , "Trends in the development of baculovirus expression vector," <i>Bio/Technology</i> , 6:47-55 (January 1988).	

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Application Number

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Filing Date

August 21, 2003

First Named Inventor

Carol J. Phelps

Group Art Unit

1632

Examiner Name

Joseph T. Woitach

Sheet 7 of 10

Attorney Docket Number 10758.105009 REV 1004

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	GA	MANSOUR, S.L., <i>et al.</i> , "Disruption of the proto-oncogene int-2 in mouse embryo-derived stem cells: a general strategy for targeting mutations to non-selectable genes," <i>Nature</i> , 336(6197):348-352 (November 24, 1988).	
	GB	McCARRICK, J.W. 3rd, <i>et al.</i> , "Positive-negative selection gene targeting with the diphtheria toxin A-chain gene in mouse embryonic stem cells," <i>Transgenic Res.</i> , 2(4):183-190 (July 2, 1993).	
	GC	McCREATH, K.J., <i>et al.</i> , "Production of gene-targeted sheep by nuclear transfer from somatic cells," <i>Nature</i> , 405:1066-1069 (July 29, 2000).	
	GD	McCURRY, K.R., <i>et al.</i> , "Human complement regulatory proteins protect swine-to-primate cardiac xenografts from humoral injury," <i>Nature Med.</i> 1(5):423-427 (May 1995).	
	GE	McKENZIE, I.F., <i>et al.</i> , "Strategies to overcome the anti-Gal alpha (1-3)Gal reaction in xenotransplantation," <i>Transplant Proc.</i> , 28(2):537 (April 1996)	
	GF	MIYAGAWA, S., <i>et al.</i> , "Remodeling of the major pig xenoantigen by N-acetylglucosaminyltransferase III in transgenic pig," <i>J. Biol. Chem.</i> , 276(42):39310-39319 (Oct. 19, 2001).	
	GG	MOREADITH, R.W., <i>et al.</i> , "Gene targeting in embryonic stem cells: the new physiology and metabolism," <i>J. Mol. Med.</i> , 75(3):208-216 (March 1997).	
	GH	MUELLER, S., <i>et al.</i> , "Chimeric pigs following blastocyst injection of transgenic porcine primordial germ cells," <i>Mol. Reprod. Dev.</i> , 54(3):244-254 (November 1999).	
	GI	MULLINS, L.J., <i>et al.</i> , "Transgenesis in the rat and larger mammals," <i>J. Clin. Invest.</i> , 97(7):1557-1560 (April 1, 1996).	
	GJ	NAGASAKA, T., <i>et al.</i> , "Inhibitory effect of α(1,2) fucosyltransferase recombinant adenoviral vector on αGal expression," <i>Transplantation Proceedings</i> , 30:3837-3838 (1998).	
	GK	ONISHI, A., <i>et al.</i> , "Pig cloning by microinjection of fetal fibroblast nuclei," <i>Science</i> , 289:1188-1190 (August 18, 2000).	
	GL	OSMAN, N., <i>et al.</i> , "Combined transgenic expression of alpha-galactosidase and alpha1,2-fucosyltransferase leads to optimal reduction in the major xenoepitope Galalpha(1,3)Gal," <i>Proc. Natl. Acad. Sci. U S A.</i> , 94(26):14677-14682 (December 23, 1997).	
	GM	PERA, M.F., <i>et al.</i> , "Human embryonic stem cells," <i>J. Cell. Sci.</i> , 113 ( Pt 1):5-10 (January 2000).	
	GN	PHELPS, C.J., <i>et al.</i> , "Production of α1,3-galactosyltransferase-deficient pigs," <i>Science</i> , 299:411-414 (Jan. 17, 2003).	
	GO	POLEJAEVA, I.A., "Cloning pigs: advances and applications," <i>Reprod.</i> , 58 (Suppl.):293-300 (2001).	
	GP	POLEJAEVA, I.A., <i>et al.</i> , "Cloned pigs produced by nuclear transfer from adult somatic cells," <i>Nature</i> , 407:86-90 (Sept. 7, 2000).	
	GQ	PORTER, A.C.G., <i>et al.</i> , "Gene Targeting: Techniques and applications to transplantation," <i>Transplantation</i> , 64:1227-1235 (Nov. 15, 1997).	

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Sheet 8 of 10				Application Number <b>10/646,970</b>
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				Group Art Unit <b>1632</b>
				Examiner Name <b>Joseph T. Woitach</b>
				Attorney Docket Number <b>10758.105009 REV 1004</b>

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	HA	PRAY, L., "Refining transgenic mice," <i>The Scientist</i> 16(13):34 (June 24, 2002) [ <a href="http://www.the-scientist.com/yr2002/jun/profile2_020624.html">http://www.the-scientist.com/yr2002/jun/profile2_020624.html</a> ].	
	HB	PURSEL V.G., <i>et al.</i> , "Progress on gene transfer in farm animals," <i>Vet. Immunol. Immunopathol.</i> , 17(1-4):303-312 (December 1987).	
	HC	RAMSOONDAR, J.J., <i>et al.</i> , "Production of $\alpha$ 1,3-galactosyltransferase-knockout cloned pigs expressing human $\alpha$ 1,2-fucosyltransferase," <i>Biol. of Reproduction</i> , 69:437-445 (online before print April 2, 2003) .	
	HD	REXROAD, C.E. Jr., <i>et al.</i> , "Production of transgenic sheep with growth-regulating genes," <i>Mol. Reprod. Dev.</i> , 1(3):164-169 (1989).	
	HE	REXROAD, C.E. Jr., <i>et al.</i> , "Insertion, expression and physiology of growth-regulating genes in ruminants," <i>J. Reprod. Fert.</i> , 41(Suppl.):119-124 (1990).	
	HF	RUBNITZ, J., <i>et al.</i> , "The minimum amount of homology required for homologous recombination in mammalian cells," <i>Mol. Cell. Biol.</i> , 4(11):2253-2258 (November 1984).	
	HG	SANDRIN, M.S., <i>et al.</i> , Identification of Gal( $\alpha$ 1,3)Gal as the major epitope for pig-to-human vascularized xenografts," <i>Transplant Rev.</i> , 8(3):134-139 (July 1994).	
	HH	SANDRIN, M.S., <i>et al.</i> , "Characterization of cDNA clones for porcine $\alpha$ (1,3)galactosyl transferase: The enzyme generating the Gal( $\alpha$ 1,3)Gal epitope," <i>Xenotransplantation</i> , 1:81-88 (1994).	
	HI	SAO, H., <i>et al.</i> , "A new marrow T cell depletion method using anti-CD6 monoclonal antibody-conjugated magnetic beads and its clinical application for prevention of acute graft-vs.-host disease in allogenic bone marrow transplantation: Results of a phase I-II trial," <i>Intl. J. Hematol.</i> , 69(1):27-35 (January 1999).	
	HJ	SASAKI, K., <i>et al.</i> , "Expression cloning of a novel Gal beta (1-3/1-4) GlcNAc alpha 2,3-sialyltransferase using lectin resistance selection," <i>J. Biol. Chem.</i> , 268(30):22782-22787 (October 25, 1993).	
	HK	SHAPER, N.L., <i>et al.</i> , "Characterization of the full length cDNA for murine beta-1,4-galactosyltransferase. Novel features at the 5'-end predict two translational start sites at two in-frame AUGs," <i>J. Biol. Chem.</i> , 263(21):10420-10428 (July 25, 1988).	
	HL	SHARMA, A., <i>et al.</i> , "Pig cells that lack the gene for $\alpha$ 1,3-galactosyltransferase express low levels of the gal antigen," <i>Transplantation</i> , 75(4):430-436 (Feb. 7, 2003).	
	HM	SIMONS, J.P., <i>et al.</i> , "Gene transfer into sheep," <i>Bio/Technology</i> , 6(1):179-183 (January 1988).	
	HN	SMITH, C.M., "Technical knockout: Gene-targeting strategies provide an avenue for studying gene function," <i>The Scientist</i> , 14(15):32 (July 24, 2000) <a href="http://www.the-scientist.com/yr2000/jul/profile_000724.html">www.the-scientist.com/yr2000/jul/profile_000724.html</a>	
	HO	STARZL, T.E., <i>et al.</i> , "Antigen localization and migration in immunity and tolerance," <i>N. Engl. J. Med.</i> , 339(26):1905-1913 (December 24, 1998).	
	HP	STARZL, T.E., <i>et al.</i> , "The biological basis of and strategies for clinical xenotransplantation," <i>Immunol. Rev.</i> , 141:213-244 (October 1994).	

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	IA	STARZL, T.E., <i>et al.</i> , "Will xenotransplantation ever be feasible?" <i>J. Am. Coll. Surg.</i> , 186(4):383-387 (April 1998).	
	IB	STOLBERG, S.G., "Could this pig save your life?" <i>N. Y. Times Magazine</i> , October 3, 1999, pp. 46-51.	
	IC	STONE, K.R., <i>et al.</i> , "Porcine and bovine cartilage transplants in cynomolgus monkey," <i>Transplantation</i> , 63(5):640-645 (March 15, 1997).	
	ID	STRAHAN, K., <i>et al.</i> , "Pig alpha 1,3galactosyltransferase: A major target for genetic manipulation in xenotransplantation," <i>Frontiers in Bioscience</i> , 1:e34-41 (July 1, 1996) [www.bioscience.org/1996/v1/e/strahan1/htmls/34-41.htm].	
	IE	STRAHAN, K.M., <i>et al.</i> , "cDNA sequence and chromosome localization of pig alpha 1,3 galactosyltransferase," <i>Immunogenetics</i> , 41(2-3):101-105 (1995).	
	IF	STRAHAN, K.M., <i>et al.</i> , "Pig alpha 1, 3galactosyltransferase: sequence of a full-length cDNA clone, chromosomal localisation of the corresponding gene, and inhibition of expression in cultured pig endothelial cells," <i>Transplant Proc.</i> , 27(1):245-246 (February 1995).	
	IG	SVENSSON, E.C., <i>et al.</i> , "Organization of the beta-galactoside alpha 2,6-sialyltransferase gene. Evidence for the transcriptional regulation of terminal glycosylation," <i>J. Biol. Chem.</i> , 265(34):20863-20868 (December 5, 1990).	
	IH	SVENSSON, E.C., <i>et al.</i> , "Regulated expression of alpha 2,6-sialyltransferase by the liver-enriched transcription factors HNF-1, DBP, and LAP," <i>J. Biol. Chem.</i> , 267(5):3466-3472 (February 15, 1992).	
	II	TANEMURA, M., <i>et al.</i> , "Differential expression of the $\alpha$ -gal epitopes (Gal $\alpha$ 1-3Gal $\beta$ 1-4GlcNAc-R) on pig and mouse organs," <i>Transplantation</i> , 69(1):187-190 (Jan. 15, 2000).	
	IJ	TANEMURA, M., <i>et al.</i> , "Reduction of the major swine xenoantigen, the $\alpha$ -galactosyl epitope by transfection of the $\alpha$ 2,3-sialyltransferase gene," <i>J. Biol. Chem.</i> , 273(26):16421-16425 (June 26, 1998).	
	IK	TEARLE, R.G., <i>et al.</i> , "The $\alpha$ -1,3-galactosyltransferase knockout mouse," <i>Transplantation</i> , 61(1):13-19 (Jan. 15, 1996).	
	IL	THALL, A.D., <i>et al.</i> , "Oocyte gal $\alpha$ 1,3gal epitopes implicated in sperm adhesion to the zona pellucida glycoprotein ZP3 are not required for fertilization in the mouse," <i>J. Biol. Chem.</i> , 270(27):21437-21440 (Sept. 15, 1995).	
	IM	THOMAS, K.R., <i>et al.</i> , "Site-directed mutagenesis by gene targeting in mouse embryo-derived stem cells," <i>Cell</i> , 51(3):503-512 (November 6, 1987).	
	IN	VANHOVE, B., <i>et al.</i> , "Porcine $\alpha$ 1,3-galactosyltransferase: Tissue-specific and regulated expression of splicing isoforms," <i>Biochim. Biophys. Acta</i> , 1356(1):1-11 (March 27, 1997).	

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	JA	VANHOVE, B., <i>et al.</i> , "Transcriptional and posttranscriptional regulation of $\alpha$ 1,3-galactosyltransfer-ase in activated endothelial cells results in decreased expression of Gal $\alpha$ 1,3Gal," <i>Glycobiology</i> , 8(5):481-487 (May 1998).	
	JB	VANHOVE, B., <i>et al.</i> , "Variability of alpha 1,3-galactosyltransferase splicing isoforms in pig tissues," <i>Transplant Proc.</i> 28(2):622-623 (April 1996).	
	JC	VAUGHAN, H.A., <i>et al.</i> , "Gal alpha(1,3)Gal is the major xenoepitope expressed on pig endothelial cells recognized by naturally occurring cytotoxic human antibodies," <i>Transplantation</i> , 58(8):879-882 (October 27, 1994).	
	JD	VIZE, P.D., <i>et al.</i> , "Introduction of a porcine growth hormone fusion gene into transgenic pigs promotes growth," <i>J. Cell Sci.</i> , 90 (Pt 2):295-300 (June 1988).	
	JE	WAGNER, "Development of transgenic pigs," <i>J. Cellular Biochem.</i> , 13B (Suppl.):164 (1989) (Abstract).	
	JF	WEINSTEIN, J., <i>et al.</i> , "Primary structure of beta-galactoside alpha 2,6-sialyltransferase. Conversion of membrane-bound enzyme to soluble forms by cleavage of the NH <sub>2</sub> -terminal signal anchor," <i>J. Biol. Chem.</i> , 262(36):17735-17743 (Dec 25, 1987).	
	JG	WHITE, D.J.G., <i>et al.</i> , "Expression of human decay accelerating factor or membrane cofactor protein genes on mouse cells inhibits lysis by human complement," <i>Transplant International</i> , 5(Suppl. 1):S648-S650 (1992).	
	JH	YAMAMOTO, F.-i., <i>et al.</i> , "Genomic organization of human histo-blood group ABO genes," <i>Glycobiology</i> , 5(1):51-58 (1995).	
	JI	YE, Y., <i>et al.</i> , "Evidence that intravenously administered a-galactosyl carbohydrates reduce baboon serum cytotoxicity to pig kidney cells (PK15) and transplanted pig hearts," <i>Transplantation</i> , 58(3):330-337 (Aug. 15, 1994).	
	JJ	YAREMA, K. <i>et al.</i> , "Characterizing glycosylation pathways," <i>Genome Biology</i> , 2(5):1-10 (May 1, 2001)	
	JK	CASTAGLIUOLO, I. <i>et al.</i> , "Clostridium difficile toxin a carboxyl-terminus peptide lacking ADP-ribosyltransferase activity acts as a mucosal adjuvant," <i>Infection and Immunity</i> , 72(5):2827-2836, (May 2004)	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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